NDA 22-256 Savella™ (milnacipran HCl) Tablets

Class of Product as per label
Selective Serotonin and Norepinephrine Reuptake Inhibitor

Applicant name
Cypress Bioscience, Inc.

Authorized Agent
Forest Laboratories, Inc.
Harborside Financial Center
Plaza III, Suite 602
Jersey City, NJ 07311

PART I: PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOAL

The goal of this REMS is to communicate the risks of Savella.

2. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each Savella prescription. Savella is packaged as a unit of use. In addition, PDFs of the medication guide will be made available for pharmacists to dispense, as well as for other healthcare providers and patients (e.g. on the Savella website).

B. Communication Plan

The REMS for Savella does not include a Communication Plan.

C. Elements To Assure Safe Use

The REMS for Savella does not include elements to assure safe use.

D. Implementation System

Because this REMS for Savella does not include elements to assure safe use, an implementation system is not required.

E. Timetable for Submission of Assessments

Cypress Bioscience, Inc. will submit REMS Assessments to the FDA by 18 months, by 3 years and in the 7th year from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Cypress Bioscience, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.

- 1st FDAAA assessment: July 2010 (by 18 months from approval)
- 2nd FDAAA assessment: January 2012 (by 3 years from approval)
- 3rd FDAAA assessment: January 2016 (in the 7th year from approval).

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22256	SUPPL-4	CYPRESS BIOSCIENCE INC	SAVELLA TABLETS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LARISSA LAPTEVA
02/02/2010